Remarks

Claims 1-15, 17 and 19-22 are pending.

The Examiner has pointed out that the Declaration executed by the inventors does not acknowledge the filing of the PCT application from which the present application was filed. A new Application Data Sheet is filed herewith identifying the PCT application and the present application.

The Examiner has also pointed out that the Abstract does not commence on a separate sheet. Applicant has amended the specification by deleting the page from the application containing the Abstract and substituting a revised Abstract.

The specification is objected to because the title on the first page of the specification differs from the title of the application. Applicant has requested that the Title of the application be amended to conform to the title on the first page of the specification. This title more accurately reflects the invention described in the application.

Claims 4, 11-13 and 17 stand objected to due to informalities in the claims. These claims have been amended to correct the informalities noted by the Examiner.

Claims 13 and 20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for due to lack of antecedent basis for the term "the solution" in the 2nd line of each claim. Claims 13 and 20 have been amended to provide terms having antecedent basis.

Claims 1-3, 5 and 7-9 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Itoi et al., U.S. Patent No. 6,159,437 ("Itoi").

Claims 1-2 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lee, WO00/15194 ("Lee").

Claims 1-2 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Roeder et al., U.S. Publication No. 2003/0031698 ("Roeder").

Claims 3-4, 6, and 8-9 stand rejected under 35 U.S.C. § 103(a) as obvious over Roeder et al., U.S. Publication No. 2003/0031698 ("Roeder").

Claims 10, 12-15 and 17 stand rejected under 35 U.S.C. § 103(a) as obvious over Kumta et al., U.S. Patent No. 7,247,288 ("Kumta") in view of Itoi.

Claims 11 and 19-22 stand rejected under 35 U.S.C. § 103(a) as obvious over Kumta in view of Roeder.

Claims 1-5, 8-15, 17 and 19-22 stand rejected on grounds of nonstautory obviousness-type double patenting as being unpatentable over claims 1-4, 9 and 14-19 of copending application no. 10/563167.

Claims 1-9 have been amended to recite that the calcium phosphate platelets are separated as described in the specification. Claims 10 and 11 have been amended to recited that the calcium phosphate platelets produced by the method have at least one of a monetite, predominant monetite or deficient apatite structure as described in the specification. No new matter is added.

As described in the specification and recited in the claims as amended, the present invention is directed to nanometric calcium phosphate platelets, the process for preparation of the platelets, and dispersions containing the platelets. As recited in claims 1-9 as amended, the calcium phosphate platelets are separated, exhibit at least one of the monetite, predominant monetite or deficient apatite structures and have a length of between 250 nm and 800 nm.

As described in the specification, the term "separated calcium phosphate platelets" means that at least 80% of the platelets have an equivalent diameter of less than or equal to 200 nm. Page 3, lines 21-26. The equivalent diameter is measured as described in the specification at page 3, line 27 to page 4, by a device for particle size analysis based on a sedimentation principle.

Claims 10-15, 17 and 19-22 as amended recite methods for preparing the separated calcium phosphate platelets.

Rejection of Claim 1-3, 5 and 7-9 Based Upon Itoi

Claims 1-3, 5 and 7-9 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Itoi et al., U.S. Patent No. 6,159,437 ("Itoi"). In order to anticipate a claim under 35 U.S.C. § 102(b), each and every element as set forth in the claim must be found in a single prior art reference. MPEP § 2131; Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Itoi does not anticipate or render the claims as amended obvious for at least two reasons: (1) Itoi describes only apatite particles and does not describe particles having a monetite, predominant monetite or deficient apatite structure as recited in claims 1-3, 5 and 7-9 as amended; and (2) Itoi does not describe separated calcium phosphate platelets having the particle size recited in claims 1-3, 5 and 7-9 as amended.

The Examiner has cited a portion of Itoi that describes "primary particles" of apatite having a "short-length" axis of 10-100 nm and a "long-length" axis of 30-300 nm. However, as noted by Itoi at col. 1, lines 25-30 and at col. 3, lines 33-35, these "primary particle" aggregate to form particles having a size of 1 μm or more. Accordingly, Itoi does not describe separated calcium phosphate platelets having the size distribution recited in the claims as amended.

Itoi describes use of a water-soluble organic solvent to disperse the apatite particles. According to Itoi, the average particle size of the apatite in the dispersion is 1 μm or less, and apatite particles of 3 microns or more are practically absent. All of the examples of Itoi show dispersions with maximum particle sizes greater than the 800 nm maximum recited in claims 1-3, 5 and 7-9 as amended. As shown in Table 1 of Itoi in the column labeled "Maximum Size", the smallest maximum is 0.97 μm (i.e. 970 nm), which is larger than the 800 nm maximum recited in the claims as amended.

Because Itoi does not describe separated calcium phosphate platelets having the type of structure and the particle size range recited in claims 1-3, 5 and 7-9 as amended, the rejection of these claims under 35 U.S.C. § 102(b) is improper and should be withdrawn.

The sole basis stated for the Examiner's obviousness rejection of claims 1-3, 5 and 7-9 based on Itoi is that Itoi anticipates the claims and "anticipation is the epitome of obviousness." For at least the reasons set forth above, Itoi does not anticipate claims 1-3, 5 and 7-9 as amended. Accordingly, the Examiner has not established a *prima facie* case of obviousness based upon Itoi, and the rejection of claims 1-5, 5 and 7-9 as obvious in view of Itoi should be withdrawn.

Rejection of Claims 1-2 Based Upon Lee

Claims 1-2 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lee, WO00/15194 ("Lee"). In order to anticipate a claim under 35 U.S.C. § 102(b), each and every element as set forth in the claim must be found in a single prior art reference. MPEP § 2131; Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Lee does not anticipate claims 1-2 at least because Lee does not describe separated calcium phosphate particles having a monetite, predominant monetite or deficient apatite structure as recited in claims 1-2 as amended.

Lee describes adjuvants and delivery vehicles comprising calcium phosphates. The calcium phosphates described by Lee are amorphous calcium phosphates or apatite calcium phosphates. Page 7, lines 22-23. Lee does not describe or suggest separate calcium phosphate platelets having a a monetite, predominant monetite or deficient apatite structure. Accordingly., Lee does not anticipate claims 1-2 as amended.

The sole basis stated for the Examiner's obviousness rejection of claims 1-2 based on Lee is that Lee anticipates the claims and "anticipation is the epitome of obviousness." For at least the reason set forth above, Lee does not anticipate claims 1-2 as amended. Accordingly, the Examiner has not established a *prima facie* case of obviousness based upon Lee, and the rejection of claims 1-5, 5 and 7-9 as obvious in view of Lee should be withdrawn.

Rejection of Claims 1-2 Based Upon Roeder

Claims 1-2 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Roeder et al., U.S. Publication No. 2003/0031698 ("Roeder"). In order to anticipate a claim under 35 U.S.C. § 102(b), each and every element as set forth in the claim must be found in a single prior art reference. MPEP § 2131; Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987).

Roeder describes composite biomaterials comprising a thermoplastic material and a calcium phosphate material embedded in the thermoplastic material. Presumably, because the calcium phosphate material is embedded in a thermoplastic material, the particles do not agglomerate to form larger particles as described in Itoi and in the specification of the present application. In any event, Roeder does not describe separate calcium phosphate platelets as recited in claims 1-2, as amended, and Roeder does not anticipate claims 1-2 for at least this reason.

Moreover, Roeder does not describe a composition wherein the calcium phosphate particles have a particle size between 250 nm and 800 nm as recited in claims 1-2. The calcium phosphate particles described in Roeder have mean lengths (the c-axis 16 shown in Fig. 2) of 1 μm to 50 μm. Paragraph [0034]. While Roeder states in Paragraph [0035] that some smaller particles can be included as well, the compositions described by Roeder necessarily include calcium phosphate particles having particle sizes much greater than the 250 nm to 800 nm range recited in claims 1-2. Accordingly, Roeder does not anticipate claims 1-2 for at least this additional reason.

The sole reason for the Examiner's obviousness rejection of claims 1-2 based on Roeder is that "anticipation is the epitome of obviousness." For at least the reasons set forth above, Roeder does not anticipate claims 1-2 as amended. Accordingly, the Examiner has not established a prima facie case of obviousness based upon Roeder, and the rejection of claims 1-2 as obvious in view of Roeder should be withdrawn.

Rejection of Claims 3-4, 6 and 8-9 As Obvious In View of Roeder

Claims 3-4, 6, and 8-9 stand rejected under 35 U.S.C. § 103(a) as obvious over Roeder et al., U.S. Publication No. 2003/0031698 ("Roeder"). The applicant respectfully maintains that the Examiner has failed to establish a prima facie case of obviousness in this case. It is well recognized that the chemical arts are generally unpredictable, as recently confirmed by the Federal Circuit in Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353 (Fed. Cir. 2008)("To the extent that an art is unpredictable, as the chemical arts often are, KSR's focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."). One skilled in the art would not have predicted the results achieved by the applicant based on the information available in the references cited by the

Examiner. Accordingly, the combination suggested by the Examiner does not establish that the claimed composition is obvious. See "Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of Supreme Court Decision in KSR International v. Teleflex, Inc.", 72 Fed. Reg. 57,526 (October 10, 2007)(in order to establish obviousness, must show a combination of prior elements according to known methods to yield predictable results).

In the KSR case, the Supreme Court confirmed the application of the factors set forth in Graham v. John Deere Co., 383 U.S. 1 (1966), in determining whether a claimed invention is obvious. Under Graham, one must consider the scope and content of the prior art and the differences between the prior art and the claims at issue to determine if an invention is obvious.

Claims 3-4, 6 and 8-9 all depend from claim 1. As discussed above, the Examiner has not established a prima facie case of obviousness of claim 1 based upon Roeder. Accordingly, for at least the reasons set forth above for claim 1, claims 3-4, 6 and 8-9 are not obvious in view of Roeder.

Rejection of Claims 10, 12-15 and 17 Based Upon Kumta in View of Itoi

Claims 10, 12-15 and 17 stand rejected under 35 U.S.C. § 103(a) as obvious over Kumta et al., U.S. Patent No. 7,247,288 ("Kumta") in view of Itoi.

Kumta describes a process for producing calcium phosphate hydroxyapatite, i.e. calcium phosphate having a hydroxyapatite structure. In the process described by Kumta, a phosphate salt is dissolved in water and a base, such as sodium hydroxide, is added to the solution to obtain a pH of about 11.5. See Example 1, col. 14, line 58 to col. 15, line 6. Thus, Kumta does not describe or suggest a process for producing separated calcium phosphate platelets having a monetite, predominant monctite or deficient apatite structure as recited in claim 10 as amended.

Moreover, Kumta does not teach a process in which the reactants are maintained at a pH of between 4 and 6.

Itoi does not address these deficiencies in Kumta. Itoi describes a hydroxyapatite slurry. Itoi does not describe calcium phosphates having a monetite, predominantly monetite or deficient apatite structure. Moreover, Itoi does not describe a process for producing calcium phosphate platelets at all. In the dispersions described by Itoi, commercially available hydroxyapatite slurries are used. See, e.g. col. 4, lines 66-67. There is nothing in Itoi that would suggest modifying the process of Kumta in any way, much less modifying the process of Kumta to arrive at the process of claims 10, 12-15 and 17 as amended.

Indeed, the Examiner has not provided any reason that one skilled in the art would modify the process for making calcium phosphate hydroxyapatite described in Kumta to arrive at the process of claims 10, 12-15 and 17 as amended, much less make such a modification with a reasonable expectation of success. Accordingly, the Examiner has not established a prima facie case of obviousness, and the rejection of claims 10, 12-15 and 17 should be withdrawn.

Rejection of Claims 11 and 19-22 Based Upon Kumta in View of Roeder

Claims 11 and 19-22 stand rejected under 35 U.S.C. § 103(a) as obvious over Kumta in view of Roeder.

As discussed above, in the process described by Kumta, a phosphate salt is dissolved in water and a base, such as sodium hydroxide, is added to the solution to obtain a pH of about 11.5. See Example 1, col. 14, line 58 to col. 15, line 6. Thus, Kumta does not describe or suggest a process for producing separated calcium phosphate platelets having a monetite, predominant monetite or deficient apatite structure as recited in claim 10 as amended. Moreover,

Kumta does not teach a process in which the reactants are maintained at a pH of between 4 and 6.

Roeder does not describe any specific process for the production of the calcium phosphate particles. Roeder merely states that the particles can be produced "in any suitable manner." Paragraph [0043]. Roeder then cites various references and provides a very general description of processes for producing calcium phosphate particles. Paragraphs [0043] and [0044]. Significantly, Roeder does not describe production of calcium phosphate by maintaining the pH of the reactants at between 4 and 6 as recited in claims 11 and 19-22 as amended. There is nothing in Roeder that would suggest modifying the process of Kumta in any way, much less modifying the process of Kumta to arrive at the process of claims 11 and 19-22 as amended.

Indeed, the Examiner has not provided any reason that one skilled in the art would modify the process for making calcium phosphate hydroxyapatite described in Kumta to arrive at the process of claims 11 and 19-22 as amended, much less make such a modification with a reasonable expectation of success. Accordingly, the Examiner has not established a prima facie case of obviousness, and the rejection of claims 11 and 19-22 should be withdrawn.

Rejection of Claims 1-5, 8-15, 17 and 19-22 Based Upon Non-Statutory Double Patenting

Claims 1-5, 8-15, 17 and 19-22 stand rejected on grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 9 and 14-19 of copending application no. 10/563167.

Claims 1-4, 9 and 14-19 of copending application no. 10/563167 recite compositions comprising calcium phosphate platelets and a polymer which complexes calcium and processes for producing the compositions. Accordingly, the compositions and processes claimed in copending application no. 10/563167 require the presence of a polymer which complexes

calcium in the composition or the reaction solution used to produce the composition. The Examiner has not identified any reason that it would be obvious for one skilled in the art to add a polymer which complexes calcium to the compositions or in the methods recited in claims 1-5, 8-15, 17 and 19-22 of the present application. While both applications recite calcium phosphate platelets, dispersions and methods of making the calcium phosphate platelets, the requirement for a polymer which complexes calcium in the compositions and methods of the claims in 1-4, 9 and 14-19 of copending application no. 10/563167 renders those claims patentably distinct from the compositions and methods recited in claims 1-5, 8-15, 17 and 19-22 of the present application. Accordingly, the rejection of claims 1-5, 8-15, 17 and 19-22 on the grounds of non-statutory obviousness-type double patenting should be withdrawn for at least this reason.

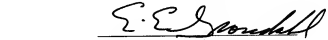
In view of the amendments to the claims and the foregoing remarks, the pending claims are believed to be allowable over the prior art of record. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance be issued. If the Examiner believes that a telephone conference with Applicants' attorney would be advantageous to the disposition of this case, and in particular if a terminal disclaimer is required for allowance, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

A Petition for a Three Month Extension of Time along with the associated fees is filed herewith. No additional fee is believed to be required. In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicant's attorney hereby authorizes that such fee be charged to Deposit Account No. 50-3569.

Dated: August 20, 2009

Respectfully submitted,



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